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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,381	09/18/2001	Raymond Bernasconi	4-30868A/C1	1717

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NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 430/2
EAST HANOVER, NJ 07936-1080

EXAMINER	
BRANNOCK, MICHAEL T	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 12/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/955,381	BERNASCONI ET AL.	
	Examiner	Art Unit	
	Michael Brannock	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-5,11,13,15 and 17-25* is/are pending in the application.

4a) Of the above claim(s) *3,5,11,13 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *4 and 17-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth on 9/15/04, have been entered in full. Claims 3, 5, 11, 13, and 15 stand withdrawn from consideration as set forth previously. Applicant is reminded that the claims are being examined only to the extent that they read on the elected invention, i.e. methods of treating Parkinson's disease.

Response to Amendment

Applicant is notified that any outstanding objection or rejection that is not expressly maintained in this Office action has been withdrawn in view of Applicant's amendments. The statutes upon which the following rejections are based can be found in the prior Office action.

Rejections:

Claims 4, 17-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as set forth previously regarding claims 9 and 10. The claims require a therapeutically effective amount of a $GABA_B$ receptor antagonist, yet the claims do not stipulate what the amount is to be effective for, i.e. there is no requirement in either claim that the amount be effective for treating the recited disorder; thus the artisan could not know whether or not he or she was practicing the claimed invention. Applicant does not appear to directly address this issue.

Additionally claims 4 and 17 (and their dependent claims) require a method for increasing neurotrophin levels in a patient with Parkinson's disease, yet the claim language does not specifically require that the methods provide any benefit regarding the symptoms or causes of the Parkinson disease, thus it is unclear if the claims encompass treatment of Parkinson disease.

Claim 24 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 25 requires that the patient be a Parkinson's patient which is already stated in parent claim 18..

Claims 4 and 17-25 are rejected under 35 U.S.C. 112, first paragraph, as set forth previously and recast below in view of Applicant's amendments. The specification while being enabling for the art recognized treatment of Alzheimer's disease, does not reasonably provide enablement for methods of treating Parkinson's disease, nor does the specification provide any meaningful use for methods of increasing neurotrophin levels in Parkinson's patients wherein this increase does not provide a treatment of Parkinson's disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The specification discloses that $GABA_B$ receptor antagonists have been found to increase the amounts of nerve growth factor

(NGF) and brain-derived nerve factor (BDNF). Based on this, the specification makes the speculation that $GABA_B$ receptor antagonists should be useful in the treatment of a variety of neurodegenerative disorders. However, no data of any kind is provided to support this speculation. One of skill in the art appreciates that the variety of disorders listed in the first paragraph of page 5 result from distinct and divergent etiologies, involve disparate cell types and have largely been found to be recalcitrant to treatments, particularly those involving neurodegeneration. Further, $GABA_B$ receptor antagonists have now been well studied in the art, and it would not be predictable that $GABA_B$ receptor antagonists would have any benefit in the treatment of Parkinson's disease. This has been born-out by Zeevalk, GD et al., Experimental Neurology 176(193-202)2002 who found that the $GABA_B$ receptor antagonist Saclofen was without effect on the malonate-induced toxicity of straital dopamine neurons in a rat model of Parkinson's disease (see the last paragraph of page 195). Moreover, Zeevalk, GD et al. review the state of the art and conclude that their findings were not surprising in view of the prior art, such art being available at the time the instant application was filed, see the middle paragraph of page 198.

Therefore due to the large quantity of experimentation necessary to try to find away to treat disorders other than Alzheimer's disease with a $GABA_B$ receptor antagonist, as taught by Yu et al., if such a way can be found, the lack of direction/guidance presented in the specification regarding which disorders, if any, are amenable to such treatment, the absence of working examples directed to same, the complex nature of the many disparate disease states contemplated by the claims, the contradictory state of the state of the prior art as reviewed by Zeevalk, GD et al and also

validated by the same authors, and the breadth of the claims which encompass perhaps the whole spectrum of disparate neurodegenerative disorders, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Applicant's arguments regarding the Zeevalk GABA transporter blockade experiments are irrelevant to the instant rejection wherein the results of the $GABA_B$ receptor antagonist experiments are cited, see above. Applicant argues that many experimental sources support the speculation that the assumed increase in neurotrophin levels as the result of the $GABA_B$ antagonist would be beneficial to the Parkinson's Patient. This argument has been fully considered but not deemed persuasive. Zeevalk et al. have done the experiment, as discussed above, and it was found not to work.

Conclusion

This application contains claims 3, 4, 5, 11, 13, 15, and 24 are drawn to an invention nonelected with traverse in Applicant's response of 10/30/2003. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, Ph.D., can be reached at (571) 272-0961. Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

MB

ELIZABETH KEMMERER
PRIMARY EXAMINER

12/6/04